PATENT SPECIFICATION

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Int. Cl.:—A 61 f 1/00 // F16k.

COMPLETE SPECIFICATION

DRAWINGS ATTACHED

Heart Valves

We, EDWARDS LABORATORIES, INC., a corporation organized under the laws of the State of California, one of the United States of America, of 624 Dyer Road, Santa Ana, State of California, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to heart valves.

According to the invention there is proposed a heart valve comprising a valve body which includes a substantially rigid base ring, a movable valve member carried by the valve body, and an upholstered sewing ring which is attached to the base ring and is made of a ring of cushion material and a covering of cloth thereon.

The invention is described further, by way of example with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a prosthetic atrioventricular valve embodying the invention for use in either the mitral or tricuspid positions;

Figure 2 is a perspective view from a different angle with the ball removed;

Figure 3 is an enlarged view on the line 3-3 of Figure 1; and

Figure 4 is an enlarged perspective view of the cloth sleeve used for the sewing ring.

The valve body comprises a base ring 10, a movable valve member 11 and a sewing ring 12. The base ring 10 is preferably made of a strong and inert metal such as Stellite (Registered Trade Mark) which is noncorrodable and has a minimum foreign body reaction with the blood. This ring is preferably cast and includes as an integral part thereof a cage 13. The movable valve member 11 preferably comprises a silicone rubber ball which is confined in the cage 13 and adapted to seat against an annular valve seat 14 in the ring 10. The ring 10 is shaped to provide an outwardly facing channel 15 extending around the ring.

The sewing ring 12 is formed in part of the cloth sleeve 20 shown in Figure 4. The material of the sleeve is preferably knitted from a synthetic fiber such as Teflon (Registered Trade Mark) so as to be freely stretchable. One edge is turned in to form a hem 21. This hemmed edge portion includes a double drawstring 22 having free ends 23 available on the outside of the sleeve for tightening the drawstring. An intermediate portion of the sleeve is equipped with a double drawstring 24 having free ends 25 available on the inside of the sleeve for tightening this drawstring. In the opposite edge of the sleeve there is a double drawstring 26 having free ends 27 available on the outside of the sleeve.

In constructing the sewing ring the sleeve 20 is first applied over the channel 15 with the hemmed edge 21 overlying the cage 13 and the opposite edge extending beyond the left side of ring 10 in Figure 3. The sleeve is positioned so that drawstring 24 overlies the channel 15. Then the drawstring 24 is tightened and its ends are tied. This holds the sleeve in position for the next operation.

A channel-shaped spreader ring 30 is then applied over the cloth in the channel 15. This ring is preferably made of a suitable inert plastic such as Teflon and contains a diagonal split so that the ring may be applied to the channel and constricted on the cloth 20. The spreader ring is clamped tightly against the cloth by one or more windings of Teflon thread 31.

The valve is then ready for placement of a flanged cushion ring 35. This ring is made of compressible material and is preferably molded from silicone foam rubber with an

L-shaped cross section having an outstanding radial flange or leg 36 and a shorter axially directed flange or leg 37. Axial flange 37 is seated on the winding 31 and on the opposite edge portions of spreader ring 30 as shown.

The left end of sleeve 20 is folded over the flange 36 and also over the flange 37, as shown. This end of the sleeve is secured by tightening drawstring 26 and tying the ends. Then the hemmed edge 21 is folded over the flange 37 on top of the first layer of cloth and the drawstring 22 is tightened and tied. After the hemmed edge 21 is folded over, the knot in drawstring 22 will be on the underside of this hem so that the knot may be tucked under and covered by the hem. Finally, the extreme edge of the hem is secured to the underlying layer of cloth by stitching 40 in the corner between flanges 36 and 37 and the cloth is pressed to make it lie smoothly on the cushion ring 35. The drawstrings and stitching 40 are preferably made of Teflon thread.

In the implantation of the valve in mitral position, the radial flange 36 is sutured to the annulus of the natural orifice and to the atrium side. The rubber cushion ring 35 conforms to any irregularities of tissue contour which may exist because of disease or other causes and forms an effective seal against the tissue. The layer of cloth 20 overlying the flange 36 provides an effective medium for the ingrowth of tissue over the whole surface of the sewing ring so that, upon healing, the sewing ring becomes permanently connected with the tissue in addition to, and independently of, the applied sutures. Both the cloth 20 and cushion ring 35 are capable of expansion and contraction, and distortion in any direction, with natural movements of the supporting tissue during pulsations of the heart so that there is no tendency for the sewing ring to pull loose from the supporting tissue.

The silicone rubber of the cushion ring 35 provides a vehicle for a medicament. The major problems in valve implantation are blood clotting and infection. Silicone rubber has the capacity to absorb an anticoagulant drug, such as heparin, or a suitable antibiotic, and exude the drug slowly over a relatively long period of time while healing is in progress. Thus, the cushion ring supplies the medicament directly at the point where it is needed. All of the well-known anticoagulants and antibiotics which are commonly used in heart operations are absorbable in and exudable from silicone rubber. The two types of drugs may be used together in ring 35, if desired.

This characteristic of silicone rubber is inherent in the nature of the material and does not depend upon a sponge-like porosity to hold the medicament in openings of visible size. The medicament is retained in the body of the rubber and not in the openings resulting from its foamy texture. Preferably, such openings are closed and sealed on the surfaces of the ring by a surface film of the rubber. In this way the rubber cushion element may function effectively as a seal against the leakage of blood and still hold the desired medicament by absorption. However, the rubber may have a somewhat open pore sponge-like texture, if desired, and still function effectively as a seal. This type of texture will accommodate ingrowth of tissue throughout the body of the ring. The described sealed surface of the present ring is punctured in many places by sutures in implantation, which affords adequate opportunity for ingrowth.

The cloth itself is not capable of holding such a medicament for slow release over a long period of time. If the medicament were to be absorbed into the cloth, it would be quickly washed away into the blood stream and become entirely ineffective long before the need for the medicament ceases to exist. For this reason the cloth is not impregnated with medicament.

The silicone rubber ball 11 may also be employed as a dispenser for absorbed medicament, if desired.

By making suitable changes in the structural details, the principal features of the present construction may be embodied in valves for other positions such as the aortic.

WHAT WE CLAIM IS:—

1. A heart valve comprising a valve body which includes a substantially rigid base ring, a movable valve member carried by the valve body, and an upholstered sewing ring which is attached to the base ring and is made of a ring of cushion material and a covering of cloth thereon.

2. A heart valve according to claim 1, wherein the cushion material is silicone rubber.

3. A heart valve according to claim 2, wherein the silicone rubber is foamed.

4. A heart valve according to claim 2 or 3, in combination with medicament absorbed in the silicone rubber.

5. A heart valve according to claim 4, wherein the medicament includes an anticoagulant.

6. A heart valve according to claim 4, wherein the medicament includes an antibiotic.

7. A heart valve according to any preceding claim, wherein the cloth covering is in the form of a sleeve surrounding and connected to the base ring and the cushion ring is secured in an annular fold of the sleeve.

8. A heart valve according to claim 7, wherein the base ring has an outwardly facing channel extending therearound and the

cloth sleeve has a portion secured in the channel.

9. A heart valve according to claim 8, wherein said portion of the sleeve is secured in the channel by a winding.

10. A heart valve according to claim 9, wherein a split ring is disposed beneath said winding and acts as a clamp around said portion of the sleeve.

11. A heart valve according to any of claims 7 to 10, wherein the sleeve has overlapped ends which are stitched to one another.

12. A heart valve according to any of claims 7 to 11, wherein the cushion ring is of L-shaped cross-section, having a radially extending flange and an axially extending portion.

13. A heart valve according to claims 11 and 12, wherein the cloth sleeve is folded around the cushion ring in such a way that its overlapped ends overlie the axially extending portion of the cushion ring.

14. A heart valve according to any of claims 7 to 13, wherein the cloth sleeve has at least one circumferential draw string for conforming the shape of the sleeve to the base and/or cushion rings.

15. A heart valve according to any preceding claim, in which the base ring constitutes a valve seat and the movable valve member is located in a cage attached to the base ring.

16. A heart valve substantially as herein described with reference to and as illustrated in the accompanying drawings.

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1 SHEET

COMPLETE SPECIFICATION

This drawing is a reproduction of the Original on a reduced scale.

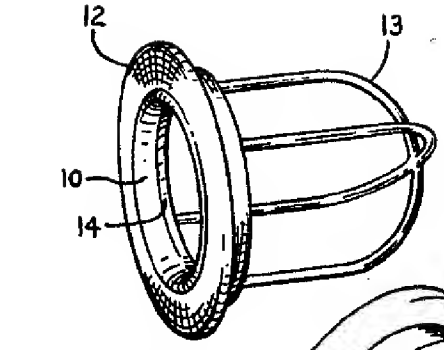

Fig. 2

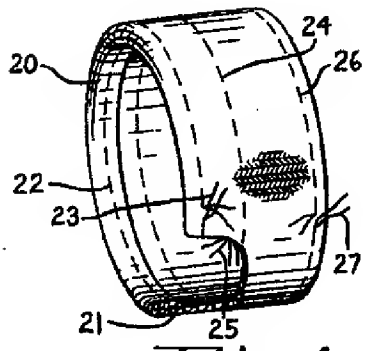

Fig. 4

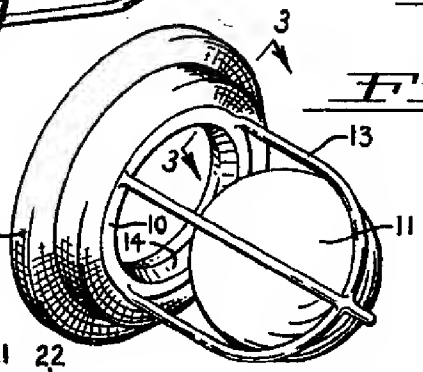

Fig. 1

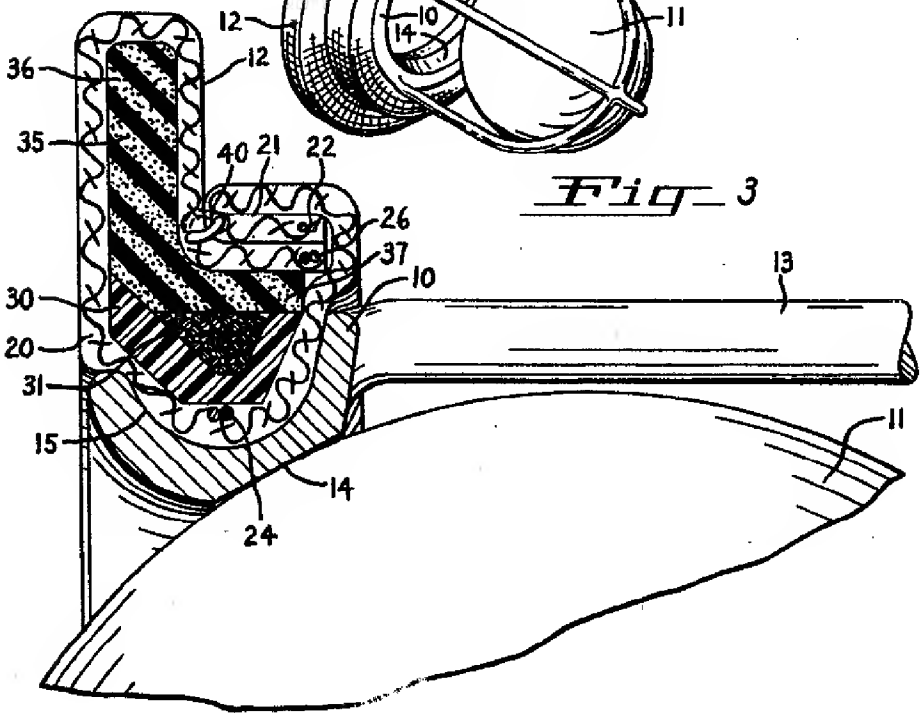

Fig. 3